

LETTER

# NORTHFIELD

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## VIA FEDERAL EXPRESS

Docket Number 95S-0158 (BB IND # 10719)  
Dockets Management Branch  
Food and Drug Administration  
Room 1061, Mail Stop HFA-305  
5630 Fisher's Lane  
Rockville, MD 20852

September 29, 2004

**RE: BB IND 10719, POLY-SFH-P INJECTION [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme®]  
Protocol RTBSE-11-(N): Publicly Disclosed Information**

Dear Sir:

Reference is made to our Investigational New Drug Application (IND) for Poly-SFH-P Injection for acute trauma, BB IND # 10719, which was originally submitted to the Office of Blood Products on October 8, 2002 (Serial No. 000). Please also refer to Protocol RTBSE-R1-11-(N) entitled "A Phase III Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection [Polymerized Human Hemoglobin (Pyridoxylated), PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries".

In conformance with 21 CFR 312.54(a) and the Draft Guidance for Industry entitled *Exception from Informed Consent Requirements for Emergency Research* (March 30, 2000) which require that Institutional Review Board (IRB) information concerning public disclosure be submitted to this Docket for clinical investigations involving an exception from informed consent [21 CFR 50.24(a)(7)(iii)], we provide documentation for the Norfolk, Virginia site:

95S-0158

SUP 31

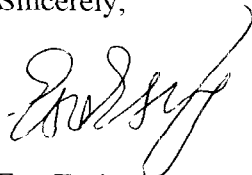
**Eastern Virginia Medical School**  
825 Fairfax Ave.  
Norfolk, Virginia 23507

**IRB: Eastern Virginia Medical School IRB**

A copy of this submission is being submitted to BB IND #10719.

If you have any comments or questions, please contact the undersigned at 847-864-3500.

Sincerely,

A handwritten signature in black ink, appearing to read 'Eva Essig', written in a cursive style.

Eva Essig, PhD  
Vice President of Regulatory Affairs and Quality